

from a location above the two renal arteries to the location near the distal region of the aneurysm.

22 48. (New). The stent-graft of claim *45*, wherein the stent system includes at least one supporting portion attached to the graft material surrounding the perimeter of the at least one renal aperture.

23 49. (New). The graft of claim *45*, wherein the unitary piece of graft material is adapted to extend from above at least one of the two renal arteries to the location near the distal end of the aneurysm without substantially extending into the either of the two renal arteries.

Remarks

Applicant thanks the Examiner for allowing claims 21, 22 and 30-33 and indicating that claims 7-10, 20 and 37 would be allowable if rewritten in independent form. Applicant has rewritten claims 7 and 37 in independent form to place claims 7-10 and 37 in condition for allowance.

Applicant has rewritten claim 38 in independent form, canceled claims 1, 6, 14, 23, 25-28, and 34-36 without prejudice and added new claims 39-49, without the introduction of new matter. For the reasons set forth below, these claims are believed to be allowable.

Applicant respectfully traverses the rejections of the canceled claims and amended claims and reserves the right to prosecute new claims directed to their subject matter and other subject matter in future prosecution.

I. Claim 19 is patentable over the cited references.

Claim 19 stands rejected under 35 USC § 103 as being anticipated by *Cox* (US Patent No. 5,824,040). Applicant respectfully traverses this rejection and, for the reasons set forth below, submits that claim 19 is patentable.

Claim 19 recites a process of bridging a defect in a main vessel using three-dimensional imaging. In the claimed process, three-dimensional imaging is used to

position a contracted graft having a sidewall aperture(s) within the main vessel and align the graft with branch vessels. The graft is then expanded to press against the main vessel.

None of the cited references, taken alone or in combination, teaches or suggests the use of three-dimensional imaging in the placement of a graft with one or more sidewall apertures. *Cox*, in particular, fails to teach or suggest the use of such imaging to place a graft. Applicants note that, in rejecting claim 19 in paragraph 4 of the Office Action, reference is made to imaging techniques used to form a graft not to imaging techniques used to place a graft. For at least these reasons, claim 19 is patentable.

II. Claim 38 is patentable over the cited references.

Claim 38 has been rewritten in independent form and stands rejected under 35 USC § 102 as being anticipated by *Cox*. Applicant respectfully traverses this rejection and for the reasons set forth below submits that claim 38 is patentable.

Claim 38 recites a stent-graft for bridging an aneurysm in an aorta, which includes a graft material defining at least one renal aperture oriented to align with one of the two renal arteries when the stent-graft is in an expanded state and a stent system for supporting the graft material in a contracted state wherein each renal aperture is contracted and the expanded state wherein each renal aperture is expanded. Claim 38 further recites that each renal aperture is larger than the orifice of the respective renal artery.

Cox teaches an endoluminal prosthesis that includes a trunk module 154 which lies below the renal arteries and a separate four branch renal hub module 158. The renal hub module 158 includes branches which extend into the renal arteries and thus have openings which are smaller than the orifices of the renal arteries. This lies in contrast with the claimed invention, which recites a renal aperture in graft material which is larger than the orifice of the renal aperture. The claimed invention can, for example, provide more efficient blood flow by not narrowing the orifice of a renal artery. For at least these reasons, claim 38 is patentable over the cited references, taken alone or in combination.

III. New claims 39-44 are patentable over the cited references.

Claim 39 recites a graft which includes graft material adapted to extend from above at least one of the two renal arteries to a region below the aneurysm without substantially extending into the either of the two renal arteries and at least one renal aperture defined by the graft material for aligning with a respective one of the two renal arteries.

Neither *Cox* nor *Tiefenbrun* (US Patent No. 5,425,765) nor any other cited reference, taken alone or in combination, teaches or suggests such features. *Cox*, for example, discloses a renal hub module 158 which includes one branch which attaches to a trunk module 154 and two renal branches which, in contrast with the claimed invention, extend into the renal arteries. *Tiefenbrun*, as noted in an earlier paper, teaches an expandable mesh stent 22 attached to one end of a tubular fabric member 12, but the tubular fabric member lies below the renal arteries and does not extend from above at least one renal artery to below the aneurysm.

For at least these reasons, claim 39 is believed to be patentable over the cited references, taken alone or in combination. Claims 40-44 recite additional features which further distinguish these claims from the cited references.

Claim 40 recites that the graft material defines a unitary tubular member. *Cox*, in contrast, teaches two separate hub modules. Claims 41 and 42 recite that the at least one renal aperture defines an opening larger than an orifice of the respective renal artery so as not to obstruct the respective renal artery when the graft material is in the expanded state. *Cox* teaches away from the claimed invention by teaching branches with opening smaller than the renal artery orifices. Claims 43 recites a stent system and claim 44 further recites that the stent system defines at least one aperture aligned with the at least one renal aperture defined by the graft material. None of the cited references, taken alone or in combination, teaches the features recited in claims 40-44. For at least these reasons, claims 40-44 are patentable over the cited references, taken alone or in combination.

IV. New claims 45-49 are patentable over the cited references.

Claim 45 recites a stent-graft which includes a stent system and a unitary piece of graft material attached to the stent system and adapted to extend from above at least one of the two renal arteries to a location near the distal end of the aneurysm. The graft

material defines at least one renal aperture which can align with a respective one of the two renal arteries and which when expanded has an opening larger than an orifice of the respective one of the two renal arteries.

None of the cited reference, taken alone or in combination, teaches or suggests such features. *Tiefenbrun*, as noted above, teaches an expandable mesh stent 22 attached to one end of a tubular fabric member 12, but the tubular fabric member lies below the renal arteries and does not extend from above at least one renal artery to below the aneurysm. *Cox*, in contrast with the claimed invention, discloses a trunk module 154 and a separate renal hub module 158. The renal hub module 158 further includes branches which extend into the renal arteries and thus have openings smaller than the renal arteries.

For at least these reasons, claim 45 is believed to be patentable over the cited references, taken alone or in combination.

Claims 45-49 recite additional features which further distinguish these claims from the cited references. Claim 45, for example, recites that the at least one renal aperture includes a single renal aperture and the unitary piece of graft material includes a first end adapted to be located between the two renal arteries and a second end adapted to be located near the distal end of the aneurysm. *Cox*, for example, teaches a renal hub module 158 which extends above both renal apertures. For these additional reasons, claims 45-49 are patentable over the cited references, taken alone or in combination.

Conclusion

In view of the above, Applicant respectfully requests withdrawal of the rejections and allowance of all pending claims.

Should the Examiner believe that an interview may be helpful in further prosecution of this case, the Examiner is invited to contact Applicant's representative at

the number listed below.

Respectfully submitted,

Wilfrido R. Castaneda,

By his attorney,

Dated: Nov. 29 2000



Tyler L. Nasiedlak
Reg. No.: 40,099

4507 Arden Avenue
Edina, MN 55424
952.836.0795

